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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/055,713

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Andrew Jamieson

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05/16/2006

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/055,713

Applicant(s)

JAMIESON ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-11, 14, 17-19 and 21-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-11, 14, 17-19 and 21-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Applicant's submission filed on March 1, 2006 has been entered.

Claims 5, 12-13, 15-16 and 20 are cancelled.

Claims 1 and 21 are currently amended.

Claims 1-4, 6-11, 14, 17-19 and 21-33 are pending and are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Election/Restrictions

Applicant traverses the restriction requirement made final in the previous office action and maintain that a separate search would not be required for each functional domain, as a search for a protein comprising any modified zinc finger would necessarily and inevitable reveal all such proteins containing attached functional domains. Applicant also points to MPEP 803.02 as indicating that restriction between related members of a Markush group is improper. Applicant further maintains that because the search and examination of the entire scope of claims 14 and 33 can be made without serious burden the restriction requirement should be withdrawn.

Applicant's arguments are unpersuasive. The Examiner maintains that a proper search of the pending claims does require a separate search for each functional domain, as a proper search is not limited only to art that would anticipate the claimed invention under 35 USC 102, but extends to any art that would render the claimed invention obvious under 35 USC 103, as well as to art that bears on the patentability of the pending claims under 35 USC 112. The Examiner also

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maintains that the members of the recited Markush group are not related, as the members of the recited Markush group do not share a substantial structural feature essential to a common utility. Consequently, the search and examination of the entire scope of claims 14 and 33 cannot be made without serious burden.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1, and claims 2-4, 6-11, 14 and 17-19 dependent thereon, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. Claim 1 as amended requires a modified plant zinc finger protein having a modified amino acid sequence wherein "(i) there are between about 5 and 50 amino acids in the backbone region of each zinc finger and wherein the backbone region is not derived from zif268 or *Xenopus* TFIIIA", which limitation does not find support in the specification as filed and thus constitutes new matter.

Claims 10 and claim 31 remain rejected, under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for isolated polynucleotides encoding the exemplified

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genus of modified plant zinc finger proteins, does not reasonably provide enablement for isolated polynucleotides encoding modified plant zinc finger proteins wherein one or more of the zinc fingers comprise any unspecified non-canonical zinc finger. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record.

Applicant's arguments filed March 1, 2006 have been fully considered but they are not persuasive.

Applicant maintains that the specification provides ample guidance on the physical properties of zinc finger proteins, including the non-canonical structure of the binding motifs set forth in claims 10 and 31, for example at pages 10-11 where the term non-canonical is defined. Applicant also maintains that the skilled artisan would know how to make and use non-canonical fingers so as to retain their binding functionality, and that any alterations to non-canonical fingers would be routine in view of the detailed disclosure in the specification regarding such engineering. Applicant additionally maintains that the Office has not and cannot present evidence reasonably establishing that these zinc finger proteins are not enabled by the specification. Applicant further points to pages 17-21 and the examples set forth in the specification as providing sufficient guidance with respect to how to modify non-canonical zinc finger proteins. (reply page 11).

The Examiner maintains that the full scope of the claimed invention is not enabled. The outstanding rejection was not predicated on the failure of the specification to disclose or define non-canonical zinc finger proteins. The outstanding rejection was predicated on the failure of the

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specification to provide guidance with respect to how to alter the structure of the zinc finger backbone of a non-canonical plant zinc finger protein relative to a corresponding established non-canonical zinc finger standard. In this regard the Examiner maintains that the skilled artisan would not know how to make and use non-canonical fingers so as to retain their binding functionality, as neither the specification (at pages 10-11, 17-21 or in the examples provided) nor the prior art provides such guidance.

Applicant also maintains that the specification need not teach and preferably omits that which is known to those working in the field, and maintains that at the time of filing the engineering of zinc finger proteins to bind to a particular target site was described in the art, for example in U.S. Patent No. 6,824,978 and U.S. Patent Application Publication No. 2003/0108880. Applicant maintains, therefore, that the Office's assertion that trial and error experimentation would be required to make and use the zinc finger proteins of claims 10 and 31 is untenable (reply pages 11-12).

The Examiner does not dispute that the specification need not teach and preferably omits that which is known to those working in the field. However, the outstanding rejection was raised and has been maintained because at the time of filing the engineering of non-canonical zinc finger proteins to bind to a particular target site was not described in the art, and is not described in the specification. With respect to U.S. Patent No. 6,824,978, the Examiner maintains that the patent does not teach the engineering of non-canonical zinc finger proteins to bind to a particular target site. With respect to U.S. Patent Application Publication No. 2003/0108880, the Examiner maintains that the publication is not representative of that which was known to those working in the field at the time the instant application was filed, as U.S. Patent Application Publication No.

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2003/0108880 was published after the filing date of the instant application and differs in disclosure from the instant application.

Claim Rejections - 35 USC § 102/103

Claims 1-4, 6-9, 11, 17-19, 21-30 and 32 remain rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Barbas et al. (US Patent No. 6,140,466, issued October 31, 2000 and filed May 27, 1997), for the reasons of record.

Applicant's arguments filed March 1, 2006 have been fully considered but they are not persuasive.

With respect to claims 1-4, 6-9, 11 and 17-19, Applicant maintains that Barbas et al. does not anticipate or render obvious the invention as currently claimed, because Barbas teaches only proteins comprising Cys2-His2 zinc fingers obtained from murine Zif268 or *Xenopus* TFIIIA, which Cys2-His2 zinc fingers are excluded from the claims 1-4, 6-9, 11 and 17-19 as currently amended. Applicant maintains that Barbas's proteins thus differ in sequence from those claimed, and therefore in structure as well.

The Examiner maintains that the amendment of claim 1 to recite that the backbone of the zinc finger is "not derived from zif268 or Zif268 or *Xenopus* TFIIIA" does not impose specific sequence or structural limitations on the claimed zinc finger proteins that allow them to be distinguished from the zinc finger proteins of Barbas. The claimed zinc finger proteins cannot be distinguished from those of Barbas because a zinc finger backbone "not derived from zif268 or Zif268 or *Xenopus* TFIIIA" and a zinc finger backbone "derived from zif268 or Zif268 or

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Xenopus TFIIIA” have the same chemical composition, i.e. they each are composed of amino acids. Further, “not derived from zif268 or Zif268 or *Xenopus* TFIIIA” does not indicate what the particular amino acid sequences or structures the claimed zinc finger proteins exhibit, or whether those sequences and structures in fact differ from those of Barbas.

With respect to claims 21-30 and 32, Applicant maintains that Barbas et al. does not anticipate or render obvious the invention as currently claimed, because the claimed proteins have naturally occurring plant zinc finger protein sequences in their backbone, whereas Barbas teaches only proteins comprising Cys2-His2 zinc fingers obtained from murine Zif268 or *Xenopus* TFIIIA. Applicant maintains that Barbas’s proteins thus differ in sequence from those claimed, and therefore in structure as well.

The Examiner first maintains that rejected claims do not require the presence of naturally occurring plant zinc finger protein sequences in their backbone. Second, the presence of naturally occurring plant zinc finger protein sequences in the backbone of the claimed zinc finger proteins would not impose specific sequence or structural limitations on the claimed zinc finger proteins that would allow them to be distinguished from the zinc finger proteins of Barbas. Zinc finger proteins comprising naturally occurring plant zinc finger protein sequences in their backbone are not distinguishable from those of Barbas, because naturally occurring plant zinc finger protein sequences and a zinc finger backbone “derived from zif268 or Zif268 or *Xenopus* TFIIIA” have the same chemical composition, i.e. they each are composed of amino acids. Further, “naturally occurring plant zinc finger protein sequences” would not indicate what

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particular amino acid sequences or structures the claimed zinc finger proteins would exhibit, or whether those sequences and structures would in fact differ from those of Barbas.

Claim Rejections - 35 USC § 103

Claims 14 and 33 remain rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Barbas et al. (US Patent No. 6,140,466, issued October 31, 2000 and filed May 27, 1997) in view of Choo et al. (US Patent No. 6,706,470, issued March 16, 2004, filed November 28, 2001, and claiming priority under 35 U.S.C. .sectn.365(c) and 35 U.S.C. .sectn.120 as a continuation of PCT/GB00/02071 filed May 30, 2000), for the reasons of record.

Applicant's arguments filed March 1, 2006 have been fully considered but they are not persuasive.

Applicant maintains that, for the reasons noted above, Barbas does not teach or suggest the subject matter of claims 1 and 21, and that claims 14 and 33 accordingly are not obvious over Barbas, alone or in combination with Choo (reply page 13).

The Examiner maintains that, for the reasons noted above, Barbas does teach or suggest the subject matter of claims 1 and 21, and that claims 14 and 33 accordingly are obvious over Barbas in combination with Choo.

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins
Primary Examiner
Art Unit 1638

CC


5/12/06